RULES
OF
THE TENNESSEE DEPARTMENT OF HEALTH
BOARD FOR LICENSING HEALTH CARE FACILITIES

CHAPTER 1200 8-10
STANDARDS FOR AMBULATORY SURGICAL TREATMENT CENTERS

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1200-8-10-.01 DEFINITIONS.

(1) Acceptable Plan of Correction. The Licensing Division approves an Ambulatory Surgical Treatment Center's plan to correct deficiencies identified during an on-site survey conducted by the Survey Division or its designated representative. The plan of correction shall be a written document and shall provide, but not limited to, the following information:

(a) How the deficiency will be corrected.

(b) Who will be responsible for correcting the deficiency.

(c) The date the deficiency will be corrected.

(d) How the facility will prevent the same deficiency from re-occurring.

(2) Accredited Record Technician (ART). A person currently accredited as such by the American Medical Records Association.

(3) Advance Directive. A written statement such as a living will, a durable power of attorney for health care or a do not resuscitate order relating to the provision of health care when the individual is incapacitated.

(4) Ambulatory surgical treatment center (ASTC). Any institution, place or building devoted primarily to the maintenance and operation of a facility for the performance of surgical procedures. Such facilities shall not provide beds or other accommodations for the stay of a patient to exceed twelve (12) hours duration, provided that the length of stay may be extended for an additional twelve (12) hours in the event such stay is deemed necessary by the attending physician, the facility medical director, or the anesthesiologist for observation or recovery, but in no event shall the length of stay exceed twenty-four (24) hours. Individual patients shall be discharged in an ambulatory condition without danger to the continued well-being of the patients or shall be transferred to a hospital. Excluded from this definition are the private physicians' and dentists' office practices. For the purposes of this rule, those medical and dental offices, facilities, and other settings at which surgical procedures exclusively are performed are ASTC's and not private office practices.

ASTC's must comply with the following for purposes of these regulations:

(a) surgical procedures performed must be limited to those procedures which are commonly performed on an inpatient basis in hospitals but may safely be performed in an ASTC;

(b) if anesthesia is required for a surgical procedure, it must be local, regional or general anesthesia and routinely be four (4) hours or less in duration;

(c) surgical procedures that generally result in extensive blood loss, require major or prolonged invasion of body cavities, or are considered emergency or life-threatening in nature may not be performed.

(5) Board. The Tennessee Board for Licensing Health Care Facilities.

(6) Cancer Treatment and Radiation Clinic. A facility in which the only procedures performed are diagnostic and therapeutic radiology, chemotherapy and related services.

(7) Cardiopulmonary Resuscitation (CPR). The administering of any means or device to support cardiopulmonary functions in a patient, whether by mechanical devices, chest compressions, mouth-to-mouth resuscitation, cardiac massage, tracheal intubation, manual or mechanical ventilators or respirators, defibrillation, the administration of drugs and/or chemical agents intended to restore cardiac and/or respiratory functions in a patient where cardiac or respiratory arrest has occurred or is believed to be imminent.

(8) Certified Registered Nurse Anesthetist. A registered nurse currently licensed by the Tennessee Board of Nursing who is currently certified as such by the American Association of Nurse Anesthetists.

(9) Clinical Laboratory Improvement Act (CLIA). The federal law requiring that clinical laboratories be approved by the U.S. Department of Health and Human Services, Health Care Financing Administration.

(10) Collaborative Plan. The formal written plan between the mid-level practitioners and licensed physician.

(11) Collaborative Practice. The implementation of the collaborative plan that outlines procedures for consultation and collaboration with other health care professionals, e.g., licensed physicians, mid-level practitioners or nurse midwives.

(12) Commissioner. Commissioner of the Tennessee Department of Health or his or her authorized representative.

(13) Competent. A patient who has decision-making capacity.

(14) Corrective Action Plan/Report. A report filed with the department by the facility after reporting an unusual event. The report must consist of the following:

(a) the action(s) implemented to prevent the reoccurrence of the unusual incident,

(b) the time frames for the action(s) to be implemented,

(c) the person(s) designated to implement and monitor the action(s), and

(d) the strategies for the measurements of effectiveness to be established.

(15) Decision-making capacity. Decision-making capacity is shown by the fact that the person is able to understand the proposed procedure, its risks and benefits, and the available alternative procedures.

(16) Dentist. A person currently licensed as such by the Tennessee Board of Dentistry.

(17) Department. The Tennessee Department of Health.

(18) Do Not Resuscitate (DNR) order. An order entered by the patient's treating physician in the patient's medical records which states that in the event the patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted. The order may contain limiting language to allow only certain types of cardiopulmonary resuscitation.

(19) Electronic Signature. The authentication of a health record document or documentation in an electronic form achieved through electronic entry of an exclusively assigned, unique identification code entered by the author of the documentation.

(20) Gastrointestinal Endoscopy Clinic. A facility in which the only procedures performed are those related to the gastrointestinal tract and other endoscopic procedures. This excludes laparoscopy and limits entry to major body cavities by needle aspiration only.

(21) General Anesthesia. An induced state of unconsciousness accompanied by partial or complete loss of protective reflexes inducing the inability to continually maintain an airway independently and respond purposefully to physical stimulation or verbal command, and produced by a pharmacological or non-pharmacological method or a combination thereof.

(22) Graduate Registered Nurse Anesthetist. A registered nurse currently licensed in Tennessee who is a graduate of a nurse anesthesia educational program that is accredited by the American Association of Nurse Anesthetist's Council on Accreditation of Nurse Anesthesia Educational Programs and awaiting initial certification examination results, provided that initial certification is accomplished within eighteen (18) months of completion of an accredited nurse anesthesia educational program.

(23) Hazardous Waste. Materials whose handling, use, storage and disposal are governed by local, state or federal regulations.

(24) Health care decision. A decision made by an individual or the individual’s health care decision-maker, regarding the individual’s health care including but not limited to:

(a) the selection and discharge of health-care providers and institutions;

(b) approval or disapproval of diagnostic tests, surgical procedures, programs of administration of medication, and orders not to resuscitate;

(c) directions to provide, withhold or withdraw artificial nutrition and hydration and all other forms of health care; and

(d) transfer to other health care facilities.

(25) Health Care Decision-maker. In the case of an incompetent patient, or a patient who lacks decision-making capacity, the patient’s health care decision-maker is one of the following: the patient’s health care agent as specified in an advance directive, the patient’s court-appointed legal guardian or conservator with health care decision-making authority, or the patient’s surrogate as determined pursuant to Rule 1200-8-10-.13 or T.C.A. §33-3-220.

(26) Hospital. Any institution, place, building or agency represented and held out to the general public as ready, willing and able to furnish care, accommodations, facilities and equipment for the use, in connection with services of a physician or dentist, to one (1) or more non-related persons who may be suffering from deformity, injury or disease or from any other condition for which nursing, medical or surgical services would be appropriate for care, diagnosis or treatment.

(27) Incompetent. A patient who has been adjudicated incompetent by a court of competent jurisdiction and has not been restored to legal capacity.

(28) Infectious Waste. Solid or liquid wastes which contain pathogens with sufficient virulence and quantity such that exposure to the waste by a susceptible host could result in an infectious disease.

(29) Lacks Decision-Making Capacity. Lacks Decision-Making Capacity means the factual demonstration by the attending physician and the medical director, or the attending physician and another physician that an individual is unable to understand:

(a) A proposed health care procedure(s), treatment(s), intervention(s), or interaction(s);

(b) The risks and benefits of such procedure(s), treatment(s), intervention(s) or interaction(s); and

(c) The risks and benefits of any available alternative(s) to the proposed procedure(s), treatment(s), intervention(s) or interaction(s).

(30) Legal Guardian. Any person authorized to act for the patient pursuant to any provision of T.C.A. §§34-5-102(4) or 34-11-101, or any successor statute thereto.

(31) Licensed Practical Nurse. A person currently licensed as such by the Tennessee Board of Nursing.

(32) Licensee. The person or entity to whom the license is issued. The licensee is held responsible for compliance with all applicable rules and regulations.

(33) Life Threatening or Serious Injury. Injury requiring the patient to undergo significant additional diagnostic or treatment measures.

(34) Medical emergency. A medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in placing the patient's health in serious jeopardy, serious impairment to bodily functions or serious dysfunction of any bodily organ or part.

(35) Medical Record. Medical histories, records, reports, summaries, diagnoses, prognoses, records of treatment and medication ordered and given, entries, x-rays, radiology interpretations and other written electronics, or graphic data prepared, kept, made or maintained in a facility that pertains to confinement or services rendered to patients admitted or receiving care.

(36) Medical Staff. An organized body composed of individuals appointed by the ambulatory surgical treatment center governing board. All members of the medical staff shall be licensed to practice in Tennessee, with the exception of interns and residents.

(37) Medically Futile Treatment. Resuscitation efforts that cannot be expected either to restore cardiac or respiratory function to the patient or to achieve the expressed goals of the informed patient. In the case of the incompetent patient, the patient's representative expresses the goals of the patient.

(38) Mid-Level Practitioner. A registered nurse licensed in Tennessee who holds a master’s degree in a clinical nursing specialty, national certification through the ANCC or American Academy of Nurse Practitioners and holds a certificate of fitness to prescribe from the Tennessee Board of Nursing.

(39) N.F.P.A. National Fire Protection Association.

(Rule 1200-8-10-.01, continued)

(40) Nurse Midwife. A person currently licensed by the Tennessee Board of Nursing as a registered nurse (R.N.) and qualified to deliver midwifery services or certified by the American College of Nurse-Midwives.

(41) Patient. Includes but is not limited to any person who is suffering from an acute or chronic illness or injury or who is crippled, convalescent or infirm, or who is in need of obstetrical, surgical, medical, nursing or supervisory care.

(42) Patient Abuse. Patient neglect, intentional infliction of pain, injury, or mental anguish. Patient abuse includes the deprivation of services by a caretaker which are necessary to maintain the health and welfare of a patient or resident; however, the withholding of authorization for or provision of medical care to any terminally ill person who has executed an irrevocable living will in accordance with the Tennessee Right to Natural Death Law, or other applicable state law, if the provision of such medical care would conflict with the terms of such living will shall not be deemed "patient abuse" for purposes of these rules.

(43) PALS. Pediatric Advance Life Support.

(44) Physician. A person currently licensed as such by the Tennessee Board of Medical Examiners or currently licensed to practice osteopathy by the Tennessee Board of Osteopathic Examination.

(45) Physician Assistant. A person who is licensed by the Tennessee Board of Medical Examiners and Committee on Physician Assistants and has obtained prescription writing authority pursuant to T.C.A. §63-19-107(2)(A).

(46) Podiatrist. A person currently licensed as such by the Tennessee Board of Registration in Podiatry.

(47) Radiological Technologist. A person currently certified as such by the American Society of Radiological Technologists.

(48) Registered Nurse (R.N.). A person currently licensed as such by the Tennessee Board of Nursing.

(49) Registered Record Administrator (RRA). A person currently registered as such by the American Medical Records Association.

(50) Shall or Must. Compliance is mandatory.

(51) Surgical Procedure. A manual or operative method performed by a licensed medical practitioner to treat diseases, injuries, conditions and/or deformities. (As related to pregnancy termination, surgical procedure excludes, but is not limited to, PAP smear or vaginal examinations, ultrasounds, amniocentesis, intramuscular injections.)

(52) Transfer. The movement of a patient at the direction of a physician or other qualified medical personnel when a physician is not readily available but does not include such movement of a patient who leaves the facility against medical advice.

(53) Unusual Event. The abuse of a patient or an unexpected occurrence or accident that results in death, life threatening or serious injury to a patient that is not related to a natural course of the patient's illness or underlying condition.

(54) Unusual Event Report. A report form designated by the department to be used for reporting an unusual event.

(Rule 1200-8-10-.01, continued)

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-216.* ***Administrative History:*** *Original rule filed July 22, 1977; effective August 22, 1977. Amendment filed August 10, 1982; effective September 9, 1982. Repeal and new rule filed June 30, 1992; effective August 14, 1992. Amendment filed March 12, 1993; effective April 26, 1993. Repeal and new rule filed March 21, 2000; effective June 4, 2000. Amendment filed April 11, 2003; effective June 25, 2003. Amendment filed April 28, 2003; effective July 12, 2003. Amendment filed June 16, 2003; effective August 30, 2003. Amendment filed May 20, 2004; effective August 3, 2004.*

1200-8-10-.02 LICENSING PROCEDURES.

(1) No person, partnership, association, corporation, or state, county, or local government unit, or any division, department, board or agency thereof, shall establish, conduct, operate or maintain in the State of Tennessee any ASTC as defined, without having a license. A license shall be issued only to the applicant named and only for the premises listed in the application for licensure. Licenses are not transferable or assignable and shall expire annually on June 30. The license shall be posted in a conspicuous place in the ASTC.

(2) In order to make application for a license:

(a) The applicant shall submit an application on a form prepared by the department.

(b) Each applicant for a license shall pay an annual license fee in the amount of eight hundred dollars ($800). The fee must be submitted with the application and is not refundable.

(c) The issuance of an application form is in no way a guarantee that the completed application will be accepted or that a license will be issued by the department. Patients shall not be admitted to the ASTC until a license has been issued. Applicants shall not hold themselves out to the public as being an ASTC until the license has been issued. A license shall not be issued until the facility is in substantial compliance with these rules and regulations including submission of all information required by Tennessee Code Annotated § 68-11-206(l), or as later amended, and all information required by the Commissioner.

(d) The applicant must prove the ability to meet the financial needs of the facility.

(e) The applicant shall not use subterfuge or other evasive means to obtain a license, such as filing for a license through a second party when an individual has been denied a license or has had a license disciplined or has attempted to avoid inspection and review process.

(3) Each ASTC, when issued a license, shall be classified according to the type of services rendered or category of patients served. The ASTC shall confine its services to those described in its license and shall advertise only the services which it is licensed to perform. The classification shall be listed on the license.

(4) A proposed change of ownership must be reported to the department a minimum of thirty (30) days prior to the change. A new application and fee must be received by the department before the license may be issued.

(a) For purposes of licensing, the licensee of an ASTC has the ultimate responsibility for the operation of the facility, including the final authority to make or control operational decisions and legal responsibility for the business management. A change of ownership occurs whenever this ultimate legal authority for the responsibility of ASTC operations is transferred.

(b) Circumstances constituting a change of ownership may include, but are not limited to, the following:

(Rule 1200-8-10-.02, continued)

1. Partnership. In the case of a partnership, the removal, addition, or substitution of a partner constitutes a change of ownership. If the facility is owned by a limited partnership, the removal of the general partner or general partners constitutes a change of ownership.

2. Corporation. The merger of a facility owner into another corporation, or the consolidation of two or more corporations, resulting in the creation of a new corporation constitutes a change of ownership. Transfer of corporate stock (even when a controlling interest), or the merger of another corporation into the originally-licensed corporation does not constitute a change of ownership.

3. Leasing. The lease of a facility's operations constitutes a change of ownership. Sale/lease -back agreements shall not be treated as changes of ownership if the lease involves the facility's entire real and personal property and if the identity of the lessee, who shall continue the operation, retains the exact same legal form as the former owner.

4. Transfers. Transfer of a facility's legal title, or a transfer between levels of government constitutes a change of ownership. A transfer between departments of the same level of government does not constitute a change of ownership.

5. Management agreements are generally not changes of ownership if the owner continues to retain ultimate authority for the operation of the facility. However, if the ultimate authority is surrendered and transferred from the owner to a new manager, then a change of ownership has occurred.

(5) To be eligible for a license or renewal of a license, each ASTC shall be periodically inspected for compliance with these regulations. If deficiencies are identified, an acceptable plan of correction shall be established and submitted to the department.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-216.* ***Administrative History:*** *Original rule filed July 22, 1977; effective August 22, 1977. Amendment filed February 26, 1985; effective March 28, 1985. Repeal and new rule filed June 30, 1992; effective August 14, 1992. Repeal and new rule filed March 21, 2000; effective June 4, 2000. Amendment filed June 16, 2003; effective August 30, 2003.*

1200-8-10-.03 DISCIPLINARY PROCEDURES.

(1) The board may suspend or revoke a license for:

(a) Violation of federal or state statutes;

(b) Violation of the rules as set forth in this chapter;

(c) Permitting, aiding or abetting the commission of any illegal act in the ASTC;

(d) Conduct or practice found by the board to be detrimental to the health, safety, or welfare of the patients of the ASTC; and

(e) Failure to renew license.

(2) The board may consider all factors which it deems relevant, including but not limited to the following when determining sanctions:

(Rule 1200-8-10-.03, continued)

(a) The degree of sanctions necessary to ensure immediate and continued compliance;

(b) The character and degree of impact of the violation on the health, safety and welfare of the patients in the facility;

(c) The conduct of the facility in taking all feasible steps or procedures necessary or appropriate to comply or correct the violation; and,

(d) Any prior violations by the facility of statutes, regulations or orders of the board.

(3) When an ambulatory surgical treatment center is found by the department to have committed a violation of this chapter, the department will issue to the facility a statement of deficiencies. Within ten (10) days of the receipt of the statement of deficiencies the facility must return a policy of correction indicating the following:

(a) How the deficiency will be corrected;

(b) The date upon which each deficiency will be corrected;

(c) What measures or systemic changes will be put in place to ensure that the deficient practice does not recur; and

(d) How the corrective action will be monitored to ensure that the deficient practice does not recur.

(4) Either failure to submit a plan of correction in a timely manner or a finding by the department that the plan of correction is unacceptable shall subject the ambulatory surgical treatment center's license to possible disciplinary action.

(5) Any licensee or applicant for a license, aggrieved by a decision or action of the department or board, pursuant to this chapter, may request a hearing before the board. The proceedings and judicial review of the board's decision shall be in accordance with the Uniform Procedures Act, T.C.A. § 4-5-101 et seq.

Authority: *T.C.A. §§4-5-202, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-216.* ***Administrative History:*** *Original rule filed July 22, 1977; effective August 22, 1977. Repeal and new rule filed June 30, 1992; effective August 14, 1992. Repeal and new rule filed March 21, 2000; effective June 4, 2000.*

1200-8-10-.04 ADMINISTRATION.

(1) The ASTC must have an effective governing body legally responsible for the conduct of the ASTC. If an ASTC does not have an organized governing body, the persons legally responsible for the conduct of the ASTC must carry out the functions specified in this chapter.

(2) The governing body shall appoint a chief executive officer or administrator who is responsible for managing the ASTC. The chief executive officer or administrator shall designate an individual to act for him or her in his or her absence, in order to provide the ASTC with administrative direction at all times.

(3) The governing body, whether it be that of the center alone or that of a parent organization, shall establish effective mechanisms to ensure the accountability of the center's medical staff and other professional personnel.

(4) The governing body shall assure that the ASTC has the financial resources to provide the services essential to the operation of the facility.

(5) Staffing shall be adequate to provide the services essential to the operation of the ASTC.

(6) The ambulatory surgical treatment center shall ensure a framework for addressing issues related to care at the end of life.

(7) The ambulatory surgical treatment center shall provide a process that assesses pain in all patients. There shall be an appropriate and effective pain management program.

(8) The ASTC shall perform only those surgical procedures which can be safely and effectively carried out on an outpatient basis.

(9) Each ASTC shall have at all times a designated Medical Director who shall be a licensed physician or dentist who shall be responsible for the direction and coordination of medical programs.

(10) Staff education programs and training sessions shall include life safety, medical equipment, utility systems, infection control and hazardous waste practices. At least two (2) on duty members of the facility shall be trained in emergency resuscitation.

(11) When licensure is applicable for a particular job, a copy of the current license must be included as a part of the personnel file. Each personnel file shall contain accurate information as to the education, training, experience and personnel background of the employee. Adequate medical screenings to exclude communicable disease shall be required of each employee.

(12) Whenever the rules and regulations of this chapter require that a licensee develop a written policy, plan, procedure, technique, or system concerning a subject, the licensee shall develop the required policy, maintain it and adhere to its provisions. An ASTC which violates a required policy also violates the rule and regulation establishing the requirement.

(13) Policies and procedures shall be consistent with professionally recognized standards of practice.

(14) No ASTC shall retaliate against or, in any manner, discriminate against any person because of a complaint made in good faith and without malice to the board, the department, the Adult Protective Services, or the Comptroller of the State Treasury. An ASTC shall neither retaliate, nor discriminate, because of information lawfully provided to these authorities, because of a person's cooperation with them, or because a person is subpoenaed to testify at a hearing involving one of these authorities.

(15) When services such as dietary, laundry or therapy services are purchased from others, the governing body shall be responsible to assure the supplier(s) meet the same local and state standards the facility would have to meet if it were providing those services itself using its own staff.

(16) The governing body shall provide for the appointment, reappointment or dismissal of members of the medical, dental, and other health professions and provide for the granting of clinical privileges.

(17) The governing body shall ensure that there is a written facility agreement with one or more acute care general hospitals licensed by the state, which will admit any patient referral who requires continuing care.

(18) Each ASTC shall specify the classification of services to be provided in the facility and list authorized surgical procedures.

(19) Where the physician-owner-operator serves as the governing body, the articles of incorporation or other written organizational plan shall describe the manner in which the owner-operator executes the governing body responsibility.

(20) Infection Control.

(a) The ASTC must provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. There must be an active performance improvement program for the prevention, control, and investigation of infections and communicable diseases.

(b) The chief executive officer or administrator shall assure that an infection control committee including members of the medical staff, nursing staff and administrative staff develops guidelines and techniques for the prevention, surveillance, control and reporting of facility infections. Duties of the committee shall include the establishment of:

1. Written infection control policies;

2. Techniques and systems for identifying, reporting, investigating and controlling infections in the facility;

3. Written procedures governing the use of aseptic techniques and procedures in all areas of the facility;

4. Written procedures concerning food handling, laundry practices, disposal of environmental and patient wastes, traffic control and visiting rules in high risk areas, sources of air pollution, and routine culturing of autoclaves and sterilizers;

5. A log of incidents related to infectious and communicable diseases;

6. A method of control used in relation to the sterilization of supplies and water, and a written policy addressing reprocessing of sterile supplies;

7. Formal provisions to educate and orient all appropriate personnel in the practice of aseptic techniques such as handwashing and scrubbing practices, proper grooming, masking and dressing care techniques, disinfecting and sterilizing techniques, and the handling and storage of patient care equipment and supplies; and,

8. Continuing education provided for all facility personnel on the cause, effect, transmission, prevention, and elimination of infections, as evidenced by front line employees verbalizing understanding of basic techniques.

(c) The chief executive officer, the medical staff and the chief nursing officer must ensure that the facility-wide performance improvement program and training programs address problems identified by the infection control committee and must be responsible for the implementation of successful corrective action plans in affected problem areas.

(d) The facility shall develop policies and procedures for testing a patient's blood for the presence of the hepatitis B virus and the HIV (AIDS) virus in the event that an employee of the facility, a student studying at the facility, or other health care provider rendering services at the facility is exposed to a patient's blood or other body fluid. The testing shall be performed at no charge to the patient, and the test results shall be confidential.

(e) The facility and its employees shall adopt and utilize standard precautions (per CDC) for preventing transmission of infections, HIV, and communicable diseases.

(Rule 1200-8-10-.04, continued)

(f) All ASTC's shall adopt appropriate policies regarding the testing of patients and staff for human immunodeficiency virus (HIV) and any other identified causative agent of acquired immune deficiency syndrome.

(21) Performance Improvement. The ASTC shall have a planned, systematic, organization-wide approach to process design and redesign, performance measurement, assessment and improvement which is approved by the designated medical staff committee of the facility, the owner and/or the governing body. This plan shall address and/or include, but is not limited to:

(a) Infection control, including post-operative surveillance;

(b) Complications arising after the patient was admitted;

(c) Documentation of periodic review of the data collected and follow-up actions;

(d) A system which identifies appropriate plans of action to correct identified quality deficiencies;

(e) Documentation that the above policies are being followed and that appropriate action is taken whenever indicated.

(22) The ASTC shall ensure a framework for addressing issues related to care at the end of life.

(23) The ASTC shall provide a process that assesses pain in all patients. There shall be an appropriate and effective pain management program.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-216.* ***Administrative History:*** *Original rule filed July 22, 1977; effective August 22, 1977. Amendment filed September10, 1991; effective October 25, 1991. Repeal and new rule filed June 30, 1992; effective August 14, 1992. Repeal and new rule filed March 21, 2000; effective June 4, 2000. Amendment filed June 18, 2002; effective September 1, 2002. Amendment filed June 16, 2003; effective August 30, 2003.*

1200-8-10-.05 ADMISSIONS, DISCHARGES, AND TRANSFERS.

(1) Every person admitted for care or treatment to any ASTC shall be under the supervision of a physician licensed to practice in Tennessee. The name, address and telephone number of the physician attending the patient shall be recorded in the patient's medical record.

(2) The above does not preclude the admission of a patient to an ASTC by a dentist or podiatrist licensed to practice in Tennessee with the concurrence of a physician member of the medical staff.

(3) This does not preclude qualified oral and maxillo-facial surgeons from admitting patients and completing the admission history and physical examination and assessing the medical risk of the procedure on their patients. A physician member of the medical staff is responsible for the management of medical problems.

(4) The facility shall ensure that no person on the grounds of race, color, national origin, or handicap, will be excluded from participation in, be denied benefits of, or otherwise subjected to discrimination in the provision of any care or service of the facility. The facility shall protect the civil rights of residents under the Civil Rights Act of 1964 and Section 504 of the Rehabilitation Act of 1973.

(5) For purposes of this chapter, the requirements for signature or countersignature by a physician, dentist, podiatrist or other person responsible for signing, countersigning or authenticating an entry may be satisfied by the electronic entry by such person of a unique code assigned exclusively to him or her, or

(Rule 1200-8-10-.05, continued)

by entry of other unique electronic or mechanical symbols, provided that such person has adopted same as his or her signature in accordance with established ASTC protocol or rules.

(6) Each ASTC must have a written transfer agreement with a local hospital.

(7) The ASTC shall develop a patient referral system both for referrals within the facility and other health care providers.

(8) The ASTC shall have available a plan for emergency transportation to a licensed local hospital.

(9) The facility must ensure continuity of care and provide an effective discharge planning process that applies to all patients. The facility's discharge planning process, including discharge policies and procedures, must be specified in writing and must:

(a) Be developed and/or supervised by a registered nurse, social worker or other appropriately qualified personnel;

(b) Begin upon admission;

(c) Be provided when identified as a need by the patient, a person acting on the patient's behalf, or by the physician; and

(d) Include the likelihood of a patient's capacity for self-care or the possibility of the patient returning to his or her pre-ambulatory surgical treatment center environment.

(10) A discharge plan is required on every patient, even if the discharge is to home.

(11) The facility must arrange for the initial implementation of the patient's discharge plan and must reassess the patient's discharge plan if there are factors that may affect continuing care needs or the appropriateness of the discharge plan.

(12) As needed, the patient and family members or interested persons must be taught and/or counseled to prepare them for post-operative care.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-216.* ***Administrative History:*** *Original rule filed July 22, 1977; effective August 22, 1977. Repeal and new rule filed June 30, 1992; effective August 14, 1992. Repeal and new rule filed March 21, 2000; effective June 4, 2000. Amendment filed June 16, 2003; effective August 30, 2003.*

1200-8-10-.06 BASIC SERVICES.

(1) Surgical Services.

(a) Facilities restricted in services they provide, e.g. those that restrict services to radiation therapy or use of local anesthetics only, may be exempted from all or part of the requirements of this rule pertaining to laboratory services, food and dietetic services, surgical services, and anesthesia services.

(b) If the facility provides surgical services, the services must be well organized and provided in accordance with acceptable standards of practice. If outpatient surgical services are offered, the services must be consistent in quality with inpatient care in accordance with the complexity of services offered.

(Rule 1200-8-10-.06, continued)

(c) A hospital may choose to separately license a portion of the facility as an Ambulatory Surgical Treatment Center; the licensure fee for such is not required.

(d) The organization of the surgical services must be appropriate to the scope of the services offered.

(e) The operating rooms must be supervised by an experienced registered nurse or a doctor of medicine or osteopathy.

(f) Licensed practical nurses (LPNs) and surgical technologists (operating room technicians) may serve as "scrub nurses" under the supervision of a registered nurse.

(g) Qualified registered nurses may perform circulating duties in the operating room. In accordance with applicable State laws and approved medical staff policies and procedures, LPNs and surgical technologists may assist in circulatory duties under the supervision of a qualified registered nurse who is immediately available to respond to emergencies.

(h) Surgical privileges must be delineated for all practitioners performing surgery in accordance with the competencies of each practitioner. The surgical service must maintain a roster of practitioners specifying the surgical privileges of each practitioner.

(i) Surgical services must be consistent with needs and resources. Policies covering surgical care must be designed to assure the achievement and maintenance of high standards of medical practice and patient care.

(j) There must be a complete history and physical work-up in the chart of every patient prior to surgery, except in emergencies. If the history has been dictated, but not yet recorded in the patient's chart, there must be a statement to that effect and an admission note in the chart by the practitioner who admitted the patient.

(k) Properly executed informed consent, advance directive, and organ donation forms must be in the patient's chart before surgery, except in emergencies.

(l) Adequate equipment and supplies must be available to the operating room suites and to the post-operative care area;

1. Call-in system (OR)
2. Cardiac monitor
3. Pulse Oximeter
4. Resuscitator
5. Defibrillator
6. Aspirator
7. Tracheotomy set

(m) A crash cart must be available and include at a minimum the following medication and supplies:

1. adrenalin (epinephrine) 1: 10,000 dilution; 10 ml

(Rule 1200-8-10-.06, continued)

2. adrenalin (epinephrine) 1:1000 dilution; 1 ml
3. atropine 0.1 mg/ml
4. benadryl (diphenhydramine)
5. calcium chloride 10%; 10ml amp
6. dextrose. 50%
7. dilantin (phentoin)
8. dopamine
9. heparin
10. inderal (proprandolol)
11. isuprel
12. lanoxin (digoxin)
13. lasix (furosemide)
14 xylocaine (lidocaine)
15. magnesium sulfate 50%
16. narcan (naloxone)
17. pronestyl (procainaimide)
18. sodium bicarbonate 50 mEq/50ml
19. solu-medrol (methylprednisolone)
20. verapamil hydrochloride
21. mazicon
22. Suction devices, endotracheal tubes, laryngoscopes, etc.,
23. Positive pressure ventilation device (e.g., Ambu) plus oxygen supply.
24. Double tourniquet for the Bier block procedure.
25. Emergency intubation equipment.
26. IV solution and IV equipment.

(n) At least one registered nurse shall be in the recovery area during the patient's recovery period.

(o) The operating room register must be complete and up-to-date.

(Rule 1200-8-10-.06, continued)

(p) An operative report describing techniques, findings, and tissues removed or altered must be written or dictated immediately following surgery and signed by the surgeon.

(q) The ASTC shall provide one or more surgical suites which shall be constructed, equipped, and maintained to assure the safety of patients and personnel.

(r) Surgical suites are required to meet the same standards as hospital operating rooms, including those using general anesthesia.

(s) The ASTC shall have separate areas for waiting rooms, recovery rooms, treatment and/or examining rooms.

(2) Anesthesiology Services. Anesthesia shall be administered by:

(a) A qualified anesthesiologist;

(b) A doctor of medicine or osteopathy (other than an anesthesiologist);

(c) A dentist, oral surgeon, or podiatrist who is qualified to administer anesthesia under State law;

(d) A certified registered nurse anesthetist (CRNA); or

(e) A graduate registered nurse anesthetist under the supervision of an anesthesiologist who is immediately available if needed.

(f) After the completion of anesthesia, patients shall be constantly attended by competent personnel until responsive and able to summon aid. Each center shall maintain a log of the inspections made prior to each day's use of the anesthesia equipment. A record of all service and maintenance performed on all anesthesia machines, vaporizers and ventilators shall also be on file.

(g) When general anesthesia and/or succinylcholine are administered, the facility shall maintain thirty-six (36) ampules of dantrolene for injection on site. If dantrolene is administered, appropriate monitoring must be provided post operatively.

(h) Written policies and procedures relative to the administration of anesthesia shall be developed and approved by the Medical Staff and governing body.

(i) Any patient receiving conscious sedation shall receive:

1. continuous EKG monitoring;

2. continuous oxygen saturations;

3. serial BP monitoring at intervals no less than every 5 minutes; and

4. supplemental oxygen therapy and immediately available:

(i) ambubag;

(ii) suction;

(iii) endotracheal tube; and

(Rule 1200-8-10-.06, continued)

(iv) crash cart.

(3) Medical Staff.

(a) The ASTC shall have a medical staff organized under written by-laws that are approved by the governing body. The medical staff of the ASTC shall define a mechanism to:

1. Assure that an optimal level of professional performance is maintained;

2. Appoint independent practitioners through a defined credentialing process;

3. Apply credentialing criteria uniformly;

4. Utilize the current license, relevant training and experience, current competence and the ability to perform requested privileges in the credentialing process; and

5. Provide for participation in required committees of the facility to ensure that quality medical care is provided to the patients.

(b) Each licensed independent practitioner shall provide care under the auspices of the facility in accordance with approved privileges.

(c) Clinical privileges shall be granted based on the practitioners' qualifications and the services provided by the facility, and shall be reviewed and/or revised at least every two (2) years.

(4) Nursing Service. A licensed registered nurse (R.N.) shall be on duty at all times. Additional appropriately trained staff shall be provided as needed to ensure that the medical needs of the patients are fully met.

(a) The ASTC shall be organized under written policies and procedures relating to patient care, establishment of standards for nursing care and mechanisms for evaluating such care and nursing services.

(b) A qualified registered nurse designated by the administrator shall be responsible for coordinating and supervising all nursing services.

(c) There shall be a sufficient staffing pattern of registered nurses to provide quality nursing care to each surgical patient from admission through discharge. Additional staff shall be on duty and available to assist the professional staff to adequately handle routine and emergency patient needs.

(d) The ASTC shall establish written procedures for emergency services which will ensure that professional staff members who have been trained in emergency resuscitation procedures shall be on duty at all times when there is a patient in the ASTC and until the patient has been discharged.

(e) Nursing care policies and procedures shall be consistent with professionally recognized standards of nursing practice and shall be in accordance with the Nurse Practice Act of the State of Tennessee and the Association of Operating Room Nurses Standards of Practice.

(f) Staff development and training shall be provided to the nursing staff and other ancillary staff in order to maintain and improve knowledge and skills. The educational/training program shall be planned, documented and conducted on a continuing basis. There shall be at least appropriate

training on equipment, safety concerns, infection control and emergency care on an annual basis.

(5) Pharmaceutical Services. The ASTC must provide drugs and biologicals in a safe and effective manner in accordance with accepted standards of practice. Such drugs and biologicals must be stored in a separate room or cabinet which shall be kept locked at all times.

(6) Ancillary Services. All ancillary or supportive health or medical services, including but not limited to, radiological, pharmaceutical, or medical laboratory services shall be provided in accordance with all applicable state and federal laws and regulations.

(7) Radiological Services. The ASTC shall provide within the facility, or through arrangement, diagnostic radiological services commensurate with the needs of the ambulatory surgical treatment center.

(a) If radiological services are provided by facility staff, the services shall be maintained free of hazards for patients and personnel.

(b) New installations of radiological equipment, and subsequent inspections for the identification of radiation hazards shall be made as specified in state and federal requirements.

(c) Personnel monitoring shall be maintained for each individual working in the area of radiation. Readings shall be on at least a monthly basis and reports kept on file and available for review.

1. Personnel - The ASTC shall have a radiologist either full-time or part-time on a consulting basis, both to supervise the service and to discharge professional radiological services.

2. The use of all radiological apparatus shall be limited to personnel designated as qualified by the radiologist; and use of fluoroscopes shall be limited to physicians.

(d) If provided under arrangement with an outside provider, the radiological services must be directed by a qualified radiologist and meet state and federal requirements.

(8) Laboratory Services.

(a) The ASTC shall provide on the premises or by written agreement with a laboratory licensed under T.C.A. 68-29-105, a clinical laboratory to provide those services commensurate with the needs and services of the ASTC.

(b) Any patient terminating pregnancy in an ASTC shall have an Rh type, documented prior to the procedure, performed on her blood. In addition, she shall be given the opportunity to receive Rh immune globulin after an appropriate crossmatch procedure is performed within a licensed laboratory.

(9) Food and Dietetic Services. If a patient will be in the facility for more than four (4) hours post-op, an appropriate diet shall be provided.

(10) Environmental Services.

(a) The facility shall provide a safe, accessible, effective and efficient environment of care consistent with its mission, service, law and regulation.

(b) The facility shall develop policies and procedures that address:

(Rule 1200-8-10-.06, continued)

1. Safety;

2. Security;

3. Control of hazardous materials and waste;

4. Emergency preparedness;

5. Life safety;

6. Medical equipment; and,

7. Utility systems.

(c) Staff shall have been oriented to and educated about the environment of care and possess knowledge and skills to perform responsibilities under the environment of care policies and procedures.

(d) Utility systems, medical equipment, life safety elements, and safety elements of the environment of care shall be maintained, tested and inspected.

(e) Safety issues shall be addressed and resolved.

(f) Appropriate staff shall participate in implementing safety recommendations and monitoring their effectiveness.

(g) The building and grounds shall be suitable to services provided and patients served.

(11) Medical Records.

(a) The ASTC shall comply with the Medical Records Act of 1974, T.C.A. § 68-11-301, et seq.

(b) A medical record shall be maintained for each person receiving medical care provided by the ASTC and shall include:

1. Patient identification;

2. Name of nearest relative or other responsible agent;

3. Identification of primary source of medical care;

4. Dates and times of visits;

5. Signed informed consent;

6. Pertinent medical history;

7. Diagnosis;

8. Physician examination report;

9. Anesthesia records of pertinent preoperative and postoperative reports including preanesthesia evaluation, type of anesthesia, technique and dosage used;

(Rule 1200-8-10-.06, continued)

10. Operative report;

11. Discharge summary, including instructions for self care and instructions for obtaining postoperative emergency care;

12. Reports of all laboratory and diagnostic procedures along with tests performed and the results authenticated by the appropriate personnel; and,

13. X-ray reports.

(c) Medical records shall be current and confidential. Medical records and copies thereof shall be made available when requested by an authorized representative of the board or the department.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-216.* ***Administrative History:*** *Original rule filed July 22, 1977; effective August 22, 1977. Amendment filed September 10, 1991; effective October 25, 1991. Repeal and new rule filed June 30, 1992; effective August 14, 1992. Repeal and new rule filed March 21, 2000; effective June 4, 2000. Amendment filed June 16, 2003; effective August 30, 2003.*

1200-8-10-.07 RESERVED.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, and 68-11-209.* ***Administrative History:*** *Original rule filed June 30, 1992; effective August 14, 1992. Repeal and new rule filed March 4, 2000; effective June 4, 2000. Amendment filed June 16, 2003; effective August 30, 2003.*

1200-8-10-.08 BUILDING STANDARDS.

(1) The ASTC must be constructed, arranged, and maintained to ensure the safety of the patient.

(2) The condition of the physical plant and the overall ASTC environment must be developed and maintained in such a manner that the safety and well-being of patients are assured.

(3) After the application and licensure fees have been submitted, the building construction plans must be submitted to the department. All new facilities shall conform to the 1999 edition of the Standard Building Code (excluding Chapter I, Administration and Chapter 11, Handicapped Accessibility), the handicap code as required by T.C.A. §68-18-204(a), the most recent edition of the ASHRAE Handbook of Fundamentals, the 2000 edition of the National Fire Protection Code (NFPA), NFPA 1 including Annex A, the 1999 National Electrical Code and the 2001 Edition of the Guidelines for Design and Construction of Hospital and Health Care Facilities. When referring to height, area or construction type, the Standard Building Code shall prevail. All new and existing facilities are subject to the requirements of the Americans with Disabilities Act (A.D.A.). Where there are conflicts between requirements in the above listed codes and regulations and provisions of this chapter, the most restrictive shall apply.

(4) All new construction and renovations to ASTC's, other than minor alterations not affecting fire and life safety or functional issues, shall be performed in accordance with the specific requirements of these regulations governing new construction in facilities, including the submission of phased construction plans and the final work drawings and the specifications to each. Phased construction plans, final work drawings, and specifications shall also be submitted prior to any change in ASTC type.

(5) No new ASTC shall hereafter be constructed, nor shall major alterations be made to existing facilities, or change in facility type be made without the prior written approval of the department, and unless in accordance with plans and specifications approved in advance by the department. Before any new ASTC is licensed or before any alteration or expansion of a licensed ASTC can be approved, the

applicant must furnish two (2) complete sets of plans and specifications to the department, together with fees and other information as required. Plans and specifications for new construction and major renovations, other than minor alterations not affecting fire and life safety or functional issues shall be prepared by or under the direction of a licensed architect and/or qualified licensed engineer.

(6) In the event that submitted materials do not appear to satisfactorily comply with 1200-8-10-.08 (3) the department shall furnish a letter to the party submitting the plans which shall list the particular items in question and request further explanation and/or confirmation of necessary modifications.

(7) Notice of satisfactory review from the department constitutes compliance with this requirement if construction begins within one hundred eighty (180) days of the date of such notice. This approval shall in no way permit and/or authorize any omission or deviation from the requirements of any restrictions, laws, regulations, ordinances, codes or rules of any responsible agency.

(8) Detailed plans shall be drawn to a scale of at least one-eighth inch equals one foot (1/8"=1'), accurately dimensioned and identifying the general arrangement of the building, the intended purpose and the fixed equipment in each room, with such additional information as the department may require.

(a) Phased construction plans shall be forwarded to the appropriate section of the department for review. After receipt of approval of phased construction plans, the owner may proceed with site grading and foundation work prior to receipt of approval of final plans and specifications with the understanding that such work is at the owner's risk and without assurance that final approval of final plans and specifications shall be granted. Final plans and specifications shall be submitted for review and approval. Final approval must be received before proceeding beyond foundation work.

(b) Review of plans does not eliminate responsibility of owner and/or architect to comply with all rules and regulations.

(9) Specifications shall supplement all drawings. They shall describe the characteristics of all materials, products and devices, unless fully described and indicated on the drawings. Specification copies should be bound in an 8½ x 11 inch folder.

(10) Review of plans and specifications shall be acknowledged in writing by the department, with copies sent to the architect and the owner, manager or other executive of the institution. The distribution of such review may be modified at the discretion of the department.

(11) All construction shall be executed in accordance with the approved plans and specifications.

(12) Drawings and specifications shall be prepared for each of the following branches of work: Architectural, Structural, Mechanical and Electrical.

(13) Architectural drawings shall include:

(a) Plot plan(s) showing property lines, finish grade, location of existing and proposed structures, roadways, walks, utilities and parking areas;

(b) Floor plan(s) showing scale drawings of typical and special rooms, indicating all fixed and movable equipment and major items of furniture;

(c) Separate life safety plans showing the compartment(s), all means of egress and exit markings, exits and travel distances, dimensions of compartments and calculation and tabulation of exit units. All fire and smoke walls must be identified;

(d) The elevation of each facade;

(e) The typical sections throughout the building;

(f) The schedule of finishes;

(g) The schedule of doors and windows;

(h) Roof plans;

(i) Details and dimensions of elevator shaft(s), car platform(s), doors, pit(s), equipment in the machine room, and the rates of car travel; and,

(j) Code analysis.

(14) Structural drawings shall include:

(a) Plans of foundations, floors, roofs and intermediate levels which show a complete design with sizes, sections and the relative location of the various members;

(b) Schedule of beams, girders and columns; and

(c) Design live load values for wind, roof, floor, stairs, guard, hand rails, and seismic.

(15) Mechanical drawings shall include:

(a) Specifications which show the complete heating, ventilating, fire protection, medical gas systems and air conditioning systems;

(b) Water supply, sewerage and HVAC piping systems;

(c) Pressure relationships which shall be shown on all floor plans;

(d) Heating, ventilating, HVAC piping, medical gas systems and air conditioning systems with all related piping and auxiliaries to provide a satisfactory installation;

(e) Water supply, sewage and drainage with all lines, risers, catch basins, manholes and cleanouts clearly indicated as to location, size, capacities, etc., and location and dimensions of septic tank and disposal field; and,

(f) Color coding to show clearly supply, return and exhaust systems.

(16) Electrical drawings shall include:

(a) A certification that all electrical work and equipment are in compliance with all applicable local codes and laws, and that all materials are currently listed by recognized testing laboratories;

(b) All electrical wiring, outlets, riser diagrams, switches, special electrical connections, electrical service entrance with service switches, service feeders and characteristics of the light and power current, and transformers when located within the building;

(c) The electrical system, which shall comply with applicable codes, and shall include:

(Rule 1200-8-10-.08, continued)

1. The nurses call system;

2. The paging system;

3. The fire alarm system; and,

4. The emergency power system including automatic services as defined by the codes.

(d) Color coding to show all items on emergency power.

(17) Final working drawings and specifications shall be accurately dimensioned and include all necessary explanatory notes, schedules and legends. The working drawings and specifications shall be complete and adequate for contract purposes. One (1) set of final plans shall be submitted to the department in such a form as approved by the department.

(18) No system of water supply, plumbing, sewage, garbage or refuse disposal shall be installed nor shall any existing system be materially altered or extended until complete plans and specifications for the installation, alteration or extension have been submitted to the department and show that all applicable codes have been met and necessary approval has been obtained.

(a) Before the facility is used, the water supply system shall be approved by the Tennessee Department of Environment and Conservation.

(b) Sewage shall be discharged into a municipal system or approved package system where available; otherwise, the sewage shall be treated and disposed of in a manner of operation approved by the Department of Environment and Conservation and shall comply with existing codes, ordinances and regulations which are enforced by cities, counties or other areas of local political jurisdiction.

(19) Rooms and areas containing radiation producing machines or radioactive material must have primary and/or secondary barriers to assure compliance with Regulations for Protection Against Radiation and security of materials. Radiation material shall be required to be stored and security must be provided in accordance with federal and state regulations to prevent exposure of the material to theft or tampering.

(20) Construction and renovation projects shall provide for the safety and protection of patients and personnel.

(21) When constructing new facilities or during major renovations to the operating suites, male and female physicians and staff shall have equitable proportional locker facilities including equal equipment, and similar amenities, with equal access to uniforms. In existing facilities the ASTC shall strive to have equitable male and female facilities. If physical changes are required, the additional areas shall maintain the flow and divisions in the sterile environments.

(22) Approved plans and specifications shall be kept at the job site.

(23) Prior to final inspection, a CD Rom disc, in TIF or DMG format, of the final approved plans including all shop drawings, sprinkler, hood and duct, calculations, addenda, specifications, etc., shall be submitted to the department.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-216.* ***Administrative History:*** *Original rule filed July 22, 1977; effective August 22, 1977. Amendment filed July 3, 1984; effective August 1, 1984. Repeal and new rule filed June 30, 1992; effective August 14, 1992. Repeal and*

(Rule 1200-8-10-.08, continued)

new rule filed March 4, 2000; effective June 4, 2000. Amendment filed February 18, 2003; effective May 4, 2003. Amendment filed June 16, 2003; effective August 30, 2003.

1200-8-10-.09 LIFE SAFETY.

(1) Any facility which complies with the required applicable building and fire safety regulations at the time the board adopts new codes or regulations will, so long as such compliance is maintained (either with or without waivers of specific provisions), be considered to be in compliance with the requirements of the new codes or regulations.

(2) The facility shall provide fire protection by the elimination of fire hazards, by the installation of necessary fire fighting equipment and by the adoption of a written fire control plan. Fire drills shall be held at least quarterly for each work shift for facility personnel in each separate patient-occupied facility building. There shall be a written report documenting the evaluation of each drill and the action recommended or taken for any deficiencies found. Records which document and evaluate these drills must be maintained for at least three (3) years.

(3) All fires shall be reported to the department within seven (7) business days. The report shall contain sufficient information to ascertain the nature and location of the fire, its probable cause and any injuries incurred by any person or persons as a result of the fire. Initial reports by the facility may omit the name(s) of patient(s) and parties involved; however, should the department find the identities of such persons to be necessary to an investigation, the facility shall provide such information.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-216.* ***Administrative History:*** *Original rule filed July 22, 1977; effective August 22, 1997. Amendment filed July 3, 1984; effective August 1, 1984. Repeal and new rule filed June 30, 1992; effective August 14, 1992. Repeal and new rule filed March 21, 2000; effective June 4, 2000. Amendment filed June 16, 2003; effective August 30, 2003.*

1200-8-10-.10 INFECTIOUS AND HAZARDOUS WASTE.

(1) Each ambulatory surgical treatment center must develop, maintain and implement written policies and procedures for the definition and handling of its infectious and hazardous wastes, these policies and procedures must comply with the standards of this section and all other applicable state and federal regulations.

(2) The following waste shall be considered to be infectious waste:

(a) Waste contaminated by patients who are isolated due to communicable disease, as provided in the U.S. Centers for Disease Control “Guidelines for Isolation Precautions in Hospitals”;

(b) Cultures and stocks of infectious agents including specimen cultures collected from medical and pathological laboratories, cultures and stocks of infectious agents from research and industrial laboratories, wastes from the production of biologicals, discarded live and attenuated vaccines, and culture dishes and devices used to transfer, inoculate, and mix cultures;

(c) Waste human blood and blood products such as serum, plasma, and other blood components.;

(d) Pathological waste, such as tissues, organs, body parts, and body fluids that are removed during surgery and autopsy;

(e) All discarded sharps (including but not limited to, hypodermic needles, syringes, pasteur pipettes, broken glass, scalpel blades) used in patient care or which have come into contact with infectious agents during use in medical, research, or industrial laboratories;

(f) Contaminated carcasses, body parts, and bedding of animals that were exposed to pathogens in research, in the production of biologicals, or in the in vivo testing of pharmaceuticals;

(g) Other waste determined to be infectious by the facility in its written policy.

(3) Infectious and hazardous waste must be segregated from other waste at the point of generation (i.e., the point at which the material becomes a waste) within the facility.

(4) Waste must be packaged in a manner that will protect waste handlers and the public from possible injury and disease that may result from exposure to the waste. Such packaging must provide for containment of the waste from the point of generation up to the point of proper treatment or disposal. Packaging must be selected and utilized for the type of waste the package will contain, how the waste will be treated and disposed, and how it will be handled and transported, prior to treatment and disposal.

(a) Contaminated sharps must be directly placed in leakproof, rigid, and puncture-resistant containers which must then be tightly sealed;

(b) Whether disposable or reusable, all containers, bags, and boxes used for containment and disposal of infectious waste must be conspicuously identified. Packages containing infectious waste which pose additional hazards (e.g., chemical, radiological) must also be conspicuously identified to clearly indicate those additional hazards;

(c) Reusable containers for infectious waste must be thoroughly sanitized each time they are emptied, unless the surfaces of the containers have been completely protected from contamination by disposable liners or other devices removed with the waste;

(d) Opaque packaging must be used for pathological waste.

(5) After packaging, waste must be handled and transported by methods ensuring containment and preserving the integrity of the packaging, including the use of secondary containment where necessary.

(a) Waste must not be compacted or ground (i.e., in a mechanical grinder) prior to treatment, except that pathological waste may be ground prior to disposal;

(b) Plastic bags of infectious waste must be transported by hand.

(6) Waste must be stored in a manner which preserves the integrity of the packaging, inhibits rapid microbial growth and putrefaction, and minimizes the potential of exposure or access by unknowing persons.

(a) Waste must be stored in a manner and location which affords protection from animals, precipitation, wind, and direct sunlight, does not present a safety hazard, does not provide a breeding place or food source for insects or rodents and does not create a nuisance.

(b) Pathological waste must be promptly treated, disposed of, or placed into refrigerated storage.

(7) In the event of spills, ruptured packaging, or other incidents where there is a loss of containment of waste, the facility must ensure that proper actions are immediately taken to:

(a) Isolate the area from the public and all except essential personnel;

(b) To the extent practicable, repackage all spilled waste and contaminated debris in accordance with the requirements of paragraph (6) of this section; and

(c) Sanitize all contaminated equipment and surfaces appropriately. Written policies and procedure must specify how this will be done.

(d) Complete incident report and maintain copy on file.

(8) Except as provided otherwise in this section a facility must treat or dispose of infectious waste by one or more of the methods specified in this part.

(a) A facility may treat infectious waste in an on-site sterilization or disinfection device, or in an incinerator or a steam sterilizer, which has been designed, constructed, operated and maintained so that infectious wastes treated in such a device are rendered non-infectious and is, if applicable, authorized for that purpose pursuant to current rules of the Department of Environment and Conservation. A valid permit or other written evidence of having complied with the Tennessee Air Pollution Control Regulations shall be available for review, if required. Each sterilizing or disinfection cycle must contain appropriate indicators to assure conditions were met for proper sterilization or disinfection of materials included in the cycle, and records kept. Proper operation of such devices must be verified at least monthly, and records of these monthly checks shall be available for review. Waste that contains toxic chemicals that would be volatilized by steam must not be treated in steam sterilizers. Infectious waste that has been rendered to a carbonized or mineralized ash shall be deemed non-infectious. Unless otherwise hazardous and subject to the hazardous waste management requirements of the current rules of the Department of Environment and Conservation, such ash shall be disposable as a (non-hazardous) solid waste under current rules of the Department of Environment and Conservation.

(b) The facility may discharge liquid or semi-liquid infectious waste to the collection sewerage system of a wastewater treatment facility which is subject to a permit pursuant to T.C.A. § 69-3-101 et seq., provided that such discharge is in accordance with any applicable terms of that permit and/or any applicable municipal sewer use requirements.

(c) Any health care facility accepting waste from another state must promptly notify the Department of Environment and Conservation, county and city public health agencies, and must strictly comply with all applicable local, state and federal regulations.

(9) The facility may have waste transported off-site for storage, treatment, or disposal. Such arrangements must be detailed in a written contract, available for review. If such off-site location is located within Tennessee, the facility must ensure that it has all necessary State and local approvals, and such approvals shall be available for review. If the off-site location is within another state, the facility must notify in writing all public health agencies with jurisdiction that the location is being used for management of the facility's waste. Waste shipped off-site must be packaged in accordance with applicable Federal and State requirements. Waste transported to a sanitary landfill in this state must meet the requirements of current rules of the Department of Environment and Conservation.

(10) Human anatomical remains which are transferred to a mortician for cremation or burial shall be exempt from the requirements of this subparagraph. Any other human limbs and recognizable organs must be incinerated or discharged (following grinding) to the sewer.

(11) All garbage, trash and other non-infectious wastes shall be stored and disposed of in a manner that must not permit the transmission of disease, create a nuisance, provide a breeding place for insects and rodents, or constitute a safety hazard. All containers for waste shall be water tight, be constructed of easily cleanable material and be kept on elevated platforms.

(12) The physical environment of the facility shall be maintained in a safe, clean and sanitary manner.

(Rule 1200-8-10-.10, continued)

(a) Any condition on the facility site conducive to the harboring or breeding of insects, rodents or other vermin shall be prohibited. Chemical substances of a poisonous nature used to control or eliminate vermin shall be properly identified. Such substances shall not be stored with or near food or medications.

(b) Cats, dogs or other animals shall not be allowed in any part of the facility except for specially trained animals for the handicapped. The facility shall designate in its policies and procedures those areas where animals will be excluded. The areas designated shall be determined based upon an assessment of the facility performed by medically trained personnel.

(c) A bed complete with mattress and pillow shall be provided. In addition, patient units shall be provided with at least one chair, a bedside table, an over bed tray and adequate storage space for toilet articles, clothing and personal belongings.

(d) Individual wash cloths, towels and bed linens must be provided for each patient. Linen shall not be interchanged from patient to patient until it has been properly laundered.

(e) Bath basin, emesis basin, bedpan and urinal shall be individually provided.

(f) Water pitchers, glasses, thermometers, emesis basins, douche apparatus, enema apparatus, urinals, mouthwash cups, bedpans and similar items of equipment coming into intimate contact with patients shall be disinfected or sterilized after each use unless individual equipment for each is provided and then sterilized or disinfected between patients and as often as necessary to maintain them in a clean and sanitary condition. Single use patient disposable items are acceptable but shall not be reused.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-216.* ***Administrative History:*** *Original rule filed July 22, 1977; effective August 22, 1977. Amendment filed July 3, 1984; effective August 1, 1984. Repeal and new rule filed June 30, 1992; effective August 14, 1992. Repeal and new rule filed March 21, 2000; effective June 4, 2000. Amendment filed June 16, 2003; effective August 30, 2003.*

1200-8-10-.11 RECORDS AND REPORTS.

(1) The Joint Annual Report of Ambulatory Surgical Treatment Centers shall be filed with the department. The forms are furnished and mailed to each ASTC by the department each year and the forms must be completed and returned to the department as required.

(2) The facility shall report information contained in the medical records of patients who have cancer or pre-cancerous or tumorous diseases as provided by existing regulations. These reports shall be sent to the Cancer Reporting System of the department on a quarterly schedule no later than six (6) months after the date of the diagnosis or treatment.

(3) The ASTC shall report to the department each case of communicable disease detected in the center. Repeated failure to report communicable diseases shall be cause for revocation of an ASTC's license.

(4) Unusual events shall be reported by the facility to the Department of Health in a format designed by the Department within seven (7) business days of the date of the identification of the abuse of a patient or an unexpected occurrence or accident that results in death, life threatening or serious injury to a patient.

(a) The following represent circumstances that could result in an unusual event that is an unexpected occurrence or accident resulting in death, life threatening or serious injury to a patient, not related to a natural course of the patient's illness or underlying condition. The circumstances that could result in an unusual event include, but are not limited to:

(Rule 1200-8-10-.11, continued)

1. medication errors;

2. aspiration in a non-intubated patient related to conscious/moderate sedation;

3. intravascular catheter related events including necrosis or infection requiring repair or intravascular catheter related pneumothorax;

4. volume overload leading to pulmonary edema;

5. blood transfusion reactions, use of wrong type of blood and/or delivery of blood to the wrong patient;

6. perioperative/periprocedural related complication(s) that occur within 48 hours of the operation or the procedure, including a procedure which results in any new central neurological deficit or any new peripheral neurological deficit with motor weakness;

7. burns of a second or third degree;

8. falls resulting in radiologically proven fractures, subdural or epidural hematoma, cerebral contusion, traumatic subarachnoid hemorrhage, and/or internal trauma, but does not include fractures resulting from pathological conditions;

9. procedure related incidents, regardless of setting and within thirty (30) days of the procedure and includes readmissions, which include:

   (i) procedure related injury requiring repair or removal of an organ;

   (ii) hemorrhage;

   (iii) displacement, migration or breakage of an implant, device, graft or drain;

   (iv) post operative wound infection following clean or clean/contaminated case;

   (v) any unexpected operation or reoperation related to the primary procedure;

   (vi) hysterectomy in a pregnant woman;

   (vii) ruptured uterus;

   (viii) circumcision;

   (ix) incorrect procedure or incorrect treatment that is invasive;

   (x) wrong patient/wrong site surgical procedure;

   (xi) unintentionally retained foreign body;

   (xii) loss of limb or organ, or impairment of limb if the impairment is present at discharge or for at least two (2) weeks after occurrence;

   (xiii) criminal acts;

   (xiv) suicide or attempted suicide;

(xv) elopement from the facility;

(xvi) infant abduction, or infant discharged to the wrong family;

(xvii) adult abduction;

(xviii) rape;

(xix) patient altercation;

(xx) patient abuse, patient neglect, or misappropriation of resident/patient funds;

(xxi) restraint related incidents; or

(xxii) poisoning occurring within the facility.

(b) Specific incidents that might result in a disruption of the delivery of health care services at the facility shall also be reported to the department, on the unusual event form, within seven (7) days after the facility learns of the incident. These specific incidents include the following:

1. strike by the staff at the facility;

2. external disaster impacting the facility;

3. disruption of any service vital to the continued safe operation of the facility or to the health and safety of its patients and personnel; and

4. fires at the facility which disrupt the provision of patient care services or cause harm to patients or staff, or which are reported by the facility to any entity, including but not limited to a fire department, charged with preventing fires.

(c) For health services provided in a "home" setting, only those unusual events actually witnessed or known by the person delivering health care services are required to be reported.

(d) Within forty (40) days of the identification of the event, the facility shall file with the department a corrective action report for the unusual event reported to the department. The department's approval of a Corrective Action Report will take into consideration whether the facility utilized an analysis in identifying the most basic or causal factor(s) that underlie variation in performance leading to the unusual event by (a) determining the proximate cause of the unusual event, (b) analyzing the systems and processes involved in the unusual event, (c) identifying possible common causes, (d) identifying potential improvements, and (e) identifying measures of effectiveness. The corrective action report shall either: (1) explain why a corrective action report is not necessary; or (2) detail the actions taken to correct any error identified that contributed to the unusual event or incident, the date the corrections were implemented, how the facility will prevent the error from recurring in the future and who will monitor the implementation of the corrective action plan.

(e) The department shall approve in writing, the corrective action report if the department is satisfied that the corrective action plan appropriately addresses errors that contributed to the unusual event and takes the necessary steps to prevent the recurrence of the errors. If the department fails to approve the corrective action report, then the department shall provide the facility with a list of actions that the department believes are necessary to address the errors. The facility shall be offered an informal meeting with the Commissioner or the Commissioner's

representative to attempt to resolve any disagreement over the corrective action report. If the department and the facility fail to agree on an appropriate corrective action plan, then the final determination on the adequacy of the corrective action report shall be made by the Board after a contested case hearing.

(f) The event report reviewed or obtained by the department shall be confidential and not subject to discovery, subpoena or legal compulsion for release to any person or entity, nor shall the report be admissible in any civil or administrative proceeding other than a disciplinary proceeding by the department or the appropriate regulatory board. The report is not discoverable or admissible in any civil or administrative action except that information in any such report may be transmitted to an appropriate regulatory agency having jurisdiction for disciplinary or license sanctions against the impacted facility. The department must reveal upon request its awareness that a specific event or incident has been reported.

(g) The department shall have access to facility records as allowed in Title 68, Chapter 11, Part 3. The department may copy any portion of a facility medical record relating to the reported event unless otherwise prohibited by rule or statute. This section does not change or affect the privilege and confidentiality provided by T.C.A. §63-6-219.

(h) The department, in developing the unusual event report form, shall establish an event occurrence code that categorizes events or specific incidents by the examples set forth above in (a) and (b). If an event or specific incident fails to come within these examples, it shall be classified as "other" with the facility explaining the facts related to the event or incident.

(i) This does not preclude the department from using information obtained under these rules in a disciplinary action commenced against a facility, or from taking a disciplinary action against a facility. Nor does this preclude the department from sharing such information with any appropriate governmental agency charged by federal or state law with regulatory oversight of the facility. However, all such information must at all times be maintained as confidential and not available to the public. Failure to report an unusual event, submit a corrective action report, or comply with a plan of correction as required herein may be grounds for disciplinary action pursuant to T.C.A. §68-11-207.

(j) The affected patient and/or the patient's family, as may be appropriate, shall also be notified of the event or incident by the facility.

(k) During the second quarter of each year, the Department shall provide the Board an aggregate report summarizing by type the number of unusual events and incidents reported by facilities to the Department for the preceding calendar year.

(l) The Department shall work with representatives of facilities subject to these rules, and other interested parties, to develop recommendations to improve the collection and assimilation of specific aggregate health care data that, if known, would track health care trends over time and identify system-wide problems for broader quality improvement. The goal of such recommendations should be to better coordinate the collection of such data, to analyze the data, to identify potential problems and to work with facilities to develop best practices to remedy identified problems. The Department shall prepare and issue a report regarding such recommendations.

(5) The ASTC shall retain legible copies of the following records and reports which shall be retained in the facility, shall be maintained in a single file, and shall be made available for inspection during normal business hours to any patient who requests to view them for thirty-six (36) months following their issuance:

(Rule 1200-8-10-.11, continued)

(a) Local fire safety inspections;

(b) Local building code inspections, if any;

(c) Fire marshal reports;

(d) Department licensure and fire safety inspections and surveys;

(e) Department quality assurance surveys, including follow-up visits, and certification inspections, if any;

(f) Federal Health Care Financing Administration surveys and inspections, if any;

(g) Orders of the Commissioner or Board, if any;

(h) Comptroller of the Treasury's audit reports and finding, if any; and,

(i) Maintenance records of all safety equipment.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-1-1004, 68-11-202, 68-11-204, 68-11-206, 68-11-207, 68-11-209, 68-11-210, 68-11-211, 68-11-213, and 68-11-216.* ***Administrative History:*** *Original rule filed July 22, 1977; effective August 22, 1977. Amendment filed September 10, 1991; effective October 25, 1991. Repeal and new rule filed June 30, 1992; effective August 14, 1992. Repeal and new rule filed March 21, 2000; effective June 4, 2000. Amendment filed April 11, 2003; effective June 25, 2003.*

1200-8-10-.12 PATIENT RIGHTS.

(1) Each patient has at least the following rights:

(a) To privacy in treatment and personal care;

(b) To be free from mental and physical abuse. Should this right be violated, the facility must notify the department within five (5) business days and the Tennessee Department of Human Services, Adult Protective Services immediately as required by T.C.A. § 71-6-101 et seq;

(c) To refuse treatment. The patient must be informed of the consequences of that decision, the refusal and its reason must be reported to the physician and documented in the medical record;

(d) To refuse experimental treatment and drugs. The patient's written consent for participation in research must be obtained and retained in his or her medical record;

(e) To have their records kept confidential and private. Written consent by the patient must be obtained prior to release of information except to persons authorized by law. If the patient is mentally incompetent, written consent is required from the patient's legal representative. The ambulatory surgical center must have policies to govern access and duplication of the patient's record;

(f) To have appropriate assessment and management of pain; and

(g) To be involved in the decision making of all aspects of their care.

(Rule 1200-8-10-.12, continued)

(2) Each patient has a right to self-determination, which encompasses the right to make choices regarding life-sustaining treatment (including resuscitative services). This right of self-determination may be effectuated by an advance directive.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-216.* ***Administrative History:*** *Original rule filed July 22, 1977; effective August 22, 1977. Repeal and new rule filed June 30, 1992; effective August 14, 1992. Repeal and new rule filed March 21, 2000; effective June 4, 2000. Amendment filed June 18, 2002; effective September 1, 2002.*

1200-8-10-.13 POLICIES AND PROCEDURES FOR HEALTH CARE DECISION-MAKING FOR INCOMPETENT PATIENTS.

(1) Pursuant to this Rule, each ambulatory surgical treatment center shall maintain and establish policies and procedures governing the designation of a health care decision-maker for making health care decisions for a patient who is incompetent or who lacks decision-making capacity, including but not limited to allowing the withholding of CPR measures from individual patients. The policies and procedures for determining when resuscitative services may be withheld must respect the patient's rights of self-determination. The ambulatory surgical treatment center must inform the patient and/or the patient's health care decision-maker of these policies and procedures upon admission or at such time as may be appropriate.

(2) The ambulatory surgical treatment center should identify, after consultation with the family or responsible party, the name of the health care decision-maker for a patient who is incompetent or who lacks decision-making capacity, who will be responsible, along with the treating physician, for making health care decisions, including but not limited to deciding on the issuance of a DNR order.

(3) Health care decisions made by a health care decision-maker must be made in accord with the patient's individual health care instructions, if any, and other wishes to the extent known to the health care decision-maker. If the patient's specific wishes are not known, decisions are to be made in accord with the health care decision-maker's determination of the patient's desires or best interests in light of the personal values and beliefs of the patient to the extent they are known.

(4) In the case of a patient who lacks decision-making capacity and who has not appointed an individual to act on his or her behalf pursuant to an advance directive and who does not have a court-appointed guardian or conservator with health care decision-making authority, documentation in the medical record must identify the patient's surrogate to make health care decisions on the patient's behalf.

(a) The patient's surrogate shall be an adult who:

1. has exhibited special care and concern for the patient, who is familiar with the patient's personal values, and who is reasonably available; and

2. consideration shall if possible be given in order of descending preference for service as a surrogate to:

(i) the patient's spouse,

(ii) the patient's adult child,

(iii) the patient's parent,

(iv) the patient's adult sibling,

(v) any other adult relative of the patient, or

(vi) any other adult who satisfies the requirement under part 1 above.

(b) If none of the individuals eligible to act as a surrogate under subparagraph (a), is reasonably available, the patient's treating physician may make health care decisions for the patient after the treating physician either (i) consults with and obtains the recommendations of an institutional ethics committee, or (ii) consults with a second physician who (A) is not directly involved in the patient's health care; (B) either (i) does not serve in a capacity of decision-making or influence or responsibility over the treating physician, or (ii) for whom the treating physician does not exert decision-making, influence or responsibility; and (C) concurs with the treating physician's decision. For the purposes of this rule, "institutional ethics committee" means a committee of a licensed health care institution which renders advice concerning ethical issues involving health care.

(5) All patients shall be presumed as having consented to CPR unless there is documentation in the medical record that the patient has specified that a DNR order be written. DNR orders may be written to exclude any portion of the CPR measures deemed to be unacceptable.

(6) In the case of an incompetent patient who has appointed an attorney in fact to act on his or her behalf pursuant to an advance directive or who has a court-appointed guardian or conservator with health care decision-making authority, documentation in the medical record must reflect that the attorney in fact, guardian or conservator has specified that a DNR order be written. In the case of a patient who lacks decision-making capacity and who has not appointed an individual to act on his or her behalf pursuant to an advance directive and who does not have a court-appointed guardian or conservator with health care decision-making authority, documentation in the medical record must identify the patient's surrogate to make health care decisions on the patient's behalf, and reflect that the patient's surrogate and the patient's treating physician have mutually specified that a DNR order be written.

(7) CPR may be withheld from the patient if in the judgment of the treating physician an attempt to resuscitate would be medically futile. Withholding and withdrawal of resuscitative services shall be regarded as identical for the purposes of these regulations.

(8) Procedures for periodic review of DNR orders must be established and maintained. The ambulatory surgical treatment center must have procedures for allowing revocation or amending DNR orders by the patient, the patient's health care decision-maker, or treating physician. Such change shall be documented in the medical record.

(9) Any treating physician who refuses to enter a DNR order in accordance with provisions set forth above, or to comply with a DNR order, shall promptly advise the patient or the patient's health care decision-maker of this decision. The treating physician shall then:

(a) Make a good faith attempt to transfer the patient to another physician who will honor the DNR order; and,

(b) Permit the patient to obtain another physician.

(10) Each ambulatory surgical treatment center shall establish, and set forth in writing, a mediation process to deal with any dispute regarding health care decisions, including DNR orders, or the determination of the health care decision-maker.

(11) This rule does not alter any requirements imposed by state or federal law, where applicable, including Title 33, the mental health and developmental disabilities law.

(Rule 1200-8-10-.13, continued)

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-224.* ***Administrative History:*** *Original rule filed June 22, 1992; effective August 6, 1992. Repeal and new rule filed March 21, 2000; effective June 4, 2000. Amendment filed April 28, 2003; effective July 12, 2003.*

1200-8-10-.14 DISASTER PREPAREDNESS.

(1) The administration of every facility shall have in effect and available for all supervisory personnel and staff, written copies of the following required disaster plans for the protection of all persons in the event of fire and other emergencies for evacuation to areas of refuge and/or evacuation from the building. A detailed log with staff signatures of training received shall be maintained. All employees shall be trained annually as required in the following plans and shall be kept informed with respect to their duties under the plans. A copy of the plans and the specific emergency numbers related to that type of disaster shall be readily available at all times. Each of the following plans shall be exercised annually:

(a) Fire Safety Procedures Plan shall include:

1. Minor fires;

2. Major fires;

3. Fighting the fire;

4. Evacuation procedures;

5. Staff functions.

(b) Tornado/Severe Weather Procedures Plan shall include:

1. Staff duties;

2. Evacuation procedures.

(c) Flood Procedure Plan, if applicable:

1. Staff duties;

2. Evacuation procedures;

3. Safety procedures following the flood.

(d) Earthquake Disaster Procedures Plan:

1. Staff duties;

2. Evacuation procedures;

3. Safety procedures;

4. Emergency services.

(2) All facilities shall participate in the Tennessee Emergency Management Agency local/county emergency plan on an annual basis. Participation includes filling out and submitting a questionnaire

(Rule 1200-8-10-.14, continued)

on a form to be provided by the Tennessee Emergency Management Agency. Documentation of participation must be maintained and shall be made available to survey staff as proof of participation.

(3) The emergency power system shall:

(a) Use either propane, gasoline or diesel fuel. The generator shall be designed to meet the facility's HVAC and essential needs and shall have a minimum of twenty-four (24) hours of fuel designed to operate at its rated load. The fuel quantity shall be based on its expected or known connected load consumption during power interruptions.

(b) Automatically transfer within ten (10) seconds in ASTC's conducting invasive surgical procedures.

(c) Be inspected monthly and exercised at the actual load and operating temperature conditions and not on dual power for at least thirty (30) minutes each month, including automatic and manual transfer of equipment. A log shall be maintained for all inspections and tests and kept on file for a minimum of three (3) years. The facility shall have trained staff familiar with the generator's operation.

(d) Emergency generators are not required if the facility does not utilize anesthesia that renders the patient incapable of self preservation. However, the facility shall have an emergency power source able to produce adequate power to run required equipment for a minimum of two (2) hours.

(4) Emergency electrical power connections shall be through a switch which shall automatically transfer the circuits to the emergency power source in case of power failure. (It is recognized that some equipment may not sustain automatic transfer and provisions will have to be made to manually change these items from a non-emergency powered outlet to an emergency powered outlet or other power source.)

(5) In the event of natural disaster or electrical power failure, no new surgical procedures shall be begun, and surgical procedures in progress shall be brought to conclusion as soon as possible.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-216.* ***Administrative History:*** *Original rule filed November 22, 1996; effective August 27, 1997. Repeal and new rule filed March 21, 2000; effective June 4, 2000. Amendment filed June 16, 2003; effective August 30, 2003.*